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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR    | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-------------------------|---------------------|------------------|
| 09/489,817      | 01/24/2000  | Muhammed Habibur Rahman | 674509-2022         | 6308             |

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EXAMINER

MCELWAIN, ELIZABETH F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 10/17/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                   |                     |
|------------------------------|-----------------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Applicant No.</b>              | <b>Applicant(s)</b> |
|                              | 09/489,817                        | RAHMAN ET AL.       |
|                              | Examiner<br>Elizabeth F. McElwain | Art Unit<br>1638    |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 36-115,117-119,121-123,125-127,129 and 130 is/are pending in the application.
- 4a) Of the above claim(s) 45-115,119,123 and 127 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 36-44,117,118,121,122,125,126,129 and 130 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 26 July 2002 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)                  4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_ .  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                  5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 18.                  6) Other:

The amendment filed July 26, 2002 has been entered.

Claims 36-44, 110-115, 117-119, 121-123, 125-127, 129 and 130 are newly amended.

Claims 116, 120, 124, 128, 131 and 132 have been cancelled.

This application contains claims 45-109 drawn to an invention nonelected with traverse

5      in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. While Paper No. 13 asserts in the remarks that claims 45-109 have been cancelled, there was no formal statement requesting cancellation of these claims in the Amendments section of the response. Therefore, these claims have not been cancelled.

10      Newly submitted claims 110-115, 119, 123 and 127 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: these claims are drawn to methods not originally claimed and are restricted from the products given that the transformed genomes of the elected invention can be made by a different method other than the method of the newly submitted claims, such as by breeding, for example.

15      Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 110-115, 119, 123 and 127 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 36-44, 117, 118, 121, 122, 125, 126, 129 and 130 are examined on the merits.

20      Please note that the title was changed from Organism in papers filed April 10, 2002.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The drawings are objected to because in Figure 1, at the bottom right corner, “B.” is recited without a species name. In addition, at the bottom left corner “B. oleracea campestris” is 5 recited, thereby including two species names. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claims 36-44, 117, 118, 121, 122, 125, 126, 129 and 130 are rejected under 35 10 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36-44, 117, 118, 121, 122, 125, 126, 129 and 130 are indefinite in the recitation of “whereby the transformed *Brassica* CC genome . . . produces seeds having a stable and uniform yellow phenotype”, given that genomes do not produce seeds, so it is unclear what is intended.

15 Claim 37 is indefinite in that it is unclear how “chromosome doubling and embryo rescue” relates to the rest of the claim.

Claim 125 is indefinite in the recitation of “transformed” twice in a row. Deletion of one will overcome the rejection.

20 Claims 36-44, 117, 118, 121, 122, 125, 126, 129 and 130 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons set forth in the last office action for claims 36-44.

Applicants arguments filed April 10, 2002 have been fully considered but they are not

5 persuasive.

Applicant asserts that one skilled in the art would be “capable of identifying, obtaining, and utilizing a *Brassica* AA genome as a vector for the transparent seed coat gene” or genes, and that techniques for obtaining the product are described and working examples of the products have been deposited.

10 The Examiner maintains that the rejection is proper and that applicants arguments are based on enablement of the invention and not to the fact that the claimed invention is not adequately described. As stated in the last office action, the claims are drawn to a *Brassica* genome having transparent seed coat gene(s). However, no genes have been described by structural or physical features. Furthermore, the claimed genomes, which consist of the 15 nucleotide sequences of every chromosome that make up the genome, have also not been described.

Claims 121, 122, 123, 125, 126, 129 and 130 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a 20 way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 129 and 130 require the seeds 13-217 and 13-219. However, since the seed claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by a deposit thereof.

- 5       The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. It is noted that applicants have deposited seeds for 13-217 and 13-219 under the depository accession numbers: NCIMB 40991 and 40992, but there is no indication in the specification as to public availability. If the deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or
- 10      declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.
- 15      If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that
- (a) during the pendency of the application, access to the invention will be afforded to the
- 20      Commissioner upon request;

- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer; (d) the 5 viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and
- (e) the deposit will be replaced if it should ever become inviable.

In addition, the specification does not provide an enabling disclosure to support that the claimed seeds have a transparent seed coat that is not obtained from a *Brassica carinata* CC genome. In fact, the examples of *Brassica* CC genomes provided in the specification are each derived from crosses with *Brassica carinata* (see pages 18-20 and 24, Figures 2 and 3). Even the seeds produced in Step IV (pages 27-28) are derived from a cross with *B. carinata*, given that the seeds named "No. 6" are derived from a cross with *B. carinata*. In addition, while the specification asserts that the *Brassica napus* genome of *B. napus* is from *B. campestris* (pages 34-35) and not *B. carinata*, there is no molecular genetic evidence to support this assertion. Given the recombination of genomes during meiosis, and the fact that all of the examples are derived from *B. carinata* at some time in their ancestry, and the fact that it is thought that four loci are involved in conferring the transparent seed coat trait, one **cannot** conclude that none of the genes required for the transparent seed coat trait came from *B. carinata*.

Given the unpredictability of identifying a multigenic trait as being derived from a particular genome, because of the occurrence of recombination during meiosis; and given the absence of guidance in the specification regarding the definitive determination that a gene or

genes are from a particular genome; the lack of working examples of a CC genome that comprises one or more transparent seed coat genes that are not derived from *Brassica carinata*; it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

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Claims 36-44, 117, 118, 121, 122, 125, 126, 129 and 130 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over either applicants' admitted state of the prior art (pages 9-10 of the specification), as stated for claims 36-44 in the last office action. In addition, the prior art taught AA genomes from *B. napus*, *B. campestris* and *B. juncea* and CC genomes from *B. napus*. In addition, a *Brassica* CC genome having a transparent seed coat not derived from *B. carinata* was taught at page 10, lines 5-10. In addition, no description is provided for genomes of the seeds 13-217 and 13-219 of claims 129 and 130. Therefore, it appears that the genomes of these seeds would be the same as the genomes taught in the prior art, and if not the same that they are so similar as to be obvious over the prior art genomes, in the absence of evidence to the contrary.

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15  
Applicant's arguments filed April 10, 2002 have been fully considered but they are not persuasive.

Applicant asserts that the rejection is improper given that the prior art references do not teach a seed with both a stable and uniform yellow phenotype, as well as improved digestibility, lower fiber content and increased oil and protein content. In addition, applicant asserts that none

of the yellow phenotype seeds taught by the prior art references are reported to have been stably maintained *in vivo*, implies a genetic instability. Applicants further state that the claimed invention is not obvious over the prior art given that the prior art fails to teach or suggest how to overcome the problem of genome instability and there is no motivation to modify the prior art

5 teachings to arrive at the present invention

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., improved digestibility, lower fiber content and increased oil and protein content, as well as plants stably transformed that produce seeds, and maintaining the trait stably *in vivo*) are not recited in the 10 rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, there is no evidence that the genomes of the prior art would not be considered stable with regard to an exogenous seed coat gene.

15 Claims 36-44, 117, 118, 129 and 130 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Meng Jinling et al (Euphytica 103(3): 329-333, 1998, Abstract provided), as stated in the last office action for claims 36-44. In addition, no description is provided for genomes of the seeds 13-217 and 13-219 of claims 129 and 130. Therefore, it appears that the genomes of these seeds would be the same as the 20 genomes taught in the prior art, and if not the same that they are so similar as to be obvious over the prior art genomes, in the absence of evidence to the contrary.

Applicant's arguments filed April 10, 2002 have been fully considered but they are not persuasive.

Applicant asserts that the rejection is improper given that interspecific breeding does not result in stable and uniform yellow seeds. Applicant further states that the plants of the present invention are different than those of Jingling et al, whose abstract asserts that the "morphology was basically towards *B. napus*", suggesting a level of uncertainty regarding the physical properties of the plants, and that traits of three species are present in the yellow seeded variety.

Applicant argues that the source of the yellow seed coat gene of No. 6 is known to be solely *B. campestris*, not *B. carinata* due to the finding that trigenomic hexaploids from *B. campestris* x *B. carinata* crosses failed to produce a transparent seed coat color. Applicants further states that since the original plant source and the quantity of yellow seed coat genes is known for the current invention, then the current invention cannot be anticipated by Jingling et al. Finally, applicant asserts that the claimed plants are also not obvious in view of Jingling et al, since the claimed plants are distinct, as stated above.

The Examiner maintains that the only physical property recited in the claims is the yellow seed color, and that there is no limitation that physical properties that exist in other species not be coded for the claimed genome. The Examiner disagrees that the source of the yellow seed coat gene of No. 6 is known to be solely *B. campestris*, not *B. carinata* due to the finding that trigenomic hexaploids from *B. campestris* x *B. carinata* crosses failed to produce a transparent seed coat color. This finding does not definitively show that the source of one or more yellow seed coat gene(s) are solely *B. campestris*, not *B. carinata*. The cited results merely shows that a

particular cross that includes genetic material from both *B. campestris*, not *B. carinata* does not result in a transparent seed coat. One cannot extrapolate from this result to the conclusion that none of the seed coat genes are from *B. carinata*. Finally, the fact that applicant knows the plant source and number of genes believed to contribute to the yellow seed coat does not differentiate 5 their claimed genome from that which was known and taught by Jingling et al.

No claims are allowed.

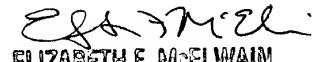
Applicant's amendment necessitated the new ground(s) of rejection presented in this 10 Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after 15 the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

- 5        If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).
- 10      Any inquiry of a general nature or relating to the status of this application should be directed to the legal analyst, Gwendolyn Payne, whose telephone number is (703) 305-2475, or to the Group receptionist whose telephone number is (703) 308-0196.

15      Elizabeth F. McElwain, Ph.D.  
October 15, 2002

  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600